IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT BRIAN PARKER, M.D.

Dr. Parker is an accomplished urologist who performs over 500 surgeries a year, including surgical implantations of synthetic midurethral slings—over 600 of which involved Ethicon's TVT-O or TVT-Secur products. Despite Dr. Parker's extensive qualifications, Plaintiffs seek to exclude his opinions about the TVT-O and TVT-Secur warnings, as well as their design and material characteristics, including safety and efficacy, degradation, cytotoxicity, contraction, pore size, mesh weight, and the characteristics of mechanically and laser-cut mesh.

The Court should deny Plaintiffs' motion because Dr. Parker is well qualified to offer his proposed testimony regarding the safety and efficacy of these products and related matters, which is well supported and based on a reliable methodology. Dr. Parker relied not only on his extensive clinical experience but also a thorough review of the medical literature, basing his conclusion on systematic reviews, meta-analyses, randomized clinical trials, and other high-quality scientific evidence. His opinions are based on "good grounds" and will assist the trier of fact in understanding the evidence and determining facts at issue—namely, whether these

products are defective and whether Plaintiffs can meet their burden of establishing general and specific causation.

As more fully explained below, Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (Ethicon) respectfully request that the Court deny Plaintiffs' motion to exclude or limit Dr. Parker's testimony.

ARGUMENTS AND AUTHORITIES

I. Dr. Parker is qualified to testify about risks that are within the common knowledge of physicians and his opinions are reliable.

Consistent with the Court's orders, Dr. Parker seeks to testify about the potential risks of the TVT-O and TVT-Secur that attend *any* pelvic reconstruction—and that are common knowledge among surgeons performing the procedures at issue here. *See* Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 17; Ex. 1, Parker 3/14/17 Dep. Tr. 184:22–185:21. The Court has "expressed no opinion" about "whether certain risks were common knowledge," and therefore has *not* precluded this expert testimony. *See, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig*., MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016). Based on his analysis, Dr. Parker proposes to testify that the risks identified by Plaintiffs' experts, and that Plaintiffs assert should have been added to the IFUs, are risks that are generally known in this surgical community or are not supported by valid scientific evidence. Dr. Parker is qualified to provide these opinions and his methodology is reliable.

As Dr. Parker notes, pelvic floor surgeons are aware of the risks that Plaintiffs' experts assert should have been included in the IFUs for TVT-O and TVT-Secur—including "the risk of pain, dyspareunia, organ or nerve damage, inflammation, fistula formation, infection, scarring, tissue contraction, neuromuscular problems, urinary problems, wound complications, bleeding, additional surgery to treat an adverse event, recurrence of SUI or failure to cure SUI, foreign

body reaction if a suture or mesh is used and erosion or extrusion of a suture." Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 17. This is because these same risks attend "[a]ny and all pelvic surgeries," whether or not the procedure involves mesh. *Id*. Dr. Parker would testify about risks commonly known to surgeons, including "the[] frequency and severity" of any of these complications because surgeons are "extensively taught and trained on the basic risks that accompany" pelvic surgeries. *Id*. In addition to learning about these risks during their training and medical education, surgeons learn about them from their reviews of the medical literature, their clinical surgical experience, their discussions with colleagues, and at public presentations and medical conferences. *Id*.

Dr. Parker's opinions that these risks are common knowledge among pelvic floor surgeons are supported by his own training and extensive clinical experience, as well as his training of other surgeons. *Id*. at 1–2. This information will be helpful to the jury because a manufacturer is not liable for a failure to warn of risks of which the physician was already independently aware. *See, e.g.*, *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 730 (E.D. Va. 1998) (citing *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 645 (4th Cir. 1981)), *aff'd*, 179 F.3d 154 (4th Cir. 1999). Indeed, Ethicon, like other medical device manufacturers, has no duty to warn pelvic-floor surgeons of risks commonly known to attend pelvic-floor surgery. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (instructing that the duty to warn is of dangers "not well known to the medical community"); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2015 WL 4944339, at *7 (S.D.W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about 'risks already known to the medical community.'"). As stated generally in the Restatement (Third) of Torts: Products Liability § 2 cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance

measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF TORTS §§ 388(b), 402A cmt. j. In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings, and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added). Moreover, the device IFUs restrict their use to surgeons familiar with traditional surgical techniques used to treat stress urinary incontinence. *E.g.*, Ex. 2, TVT-O IFU, HMESH_ETH_11043472 (stating device should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device"); Ex. 3, TVT-Secur IFU, ETH.MESH.02340576 ("Only physicians trained in the surgical treatment of stress urinary incontinence should use the product.").

Plaintiffs nonetheless argue that Dr. Parker's opinions should be excluded because he is not familiar with the standards applicable to medical device IFUs or the process by which IFUs are developed and approved. Pls.' Mem. (Dkt. 3674) at 4. But Dr. Parker need not be familiar with these standards to testify about the risks common to pelvic surgeries—mesh or nonmesh—of which all pelvic surgeons are necessarily aware because he is not offering an opinion that the TVT IFU is adequate as Plaintiffs claim.

Ethicon is mindful of the Court's Wave 1 ruling that experts without additional regulatory expertise on product labeling and compliance cannot testify "about what an IFU should or should not include." *See, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 (S.D.W. Va. Aug. 31, 2016). Dr. Parker will not be offering opinions about what should or should not be included in an IFU. Ethicon respectfully submits, however, that risks that are within the common knowledge of physicians are risks that

would not, as a matter of logic, be included in an IFU. This logical result, however, does not mean that an expert's common-knowledge testimony should be excluded under the Court's exclusionary "additional expertise" directive. Instead, the Court's directive goes to the lack of expertise in regulatory requirements and compliance, not whether a particular risk is within the common knowledge of physicians. *See Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015) (distinguishing between an expert's expertise "in the requirements for product labeling" and the expert's qualifications as a practicing physician to testify about risks provided in the text of the product's labeling).

In accordance with this distinction and the Court's limitations, Dr. Parker will not testify about the regulatory requirements for product labeling for the IFUs at issue here or what the IFU should or should not include. But he is qualified by education, training, and experience to give opinions about what risks are within the common knowledge of surgeons who perform pelvic-floor surgery. Any disagreement Plaintiffs may have with Dr. Parker's opinions on this issue goes to weight, not admissibility.

He relies on his training in surgical procedures and their inherent risks, his training of other surgeons on those topics, and his review not only of the IFUs of the TVT products, but on FDA considerations of the risks of both mesh and non-mesh surgeries as well. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 17. Dr. Parker's opinions do not touch on regulatory areas for which additional expertise would be required. They are well-supported and should be deemed reliable.

II. Dr. Parker is qualified to offer his opinions on mesh properties and his opinions are reliable.

A. Dr. Parker is qualified by education, training, and experience.

Dr. Parker is a board-certified urologist who performs more than 500 surgeries per year. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 1. He has performed over 200 TVT-O procedures and over 400 procedures with TVT-Secur. *Id*. at 2. He is a proctor for Coloplast's Altis sling, and has performed more than 300 procedures with that device. *Id*. He has also performed mesh-revision procedures. *Id*. at 20. In addition to his extensive clinical experience, Dr. Parker thoroughly reviewed the peer-reviewed scientific literature. He reviewed "hundreds and hundreds" of scientific studies and articles, discussing more than 45 of these studies and articles in his report. Ex. 1, Parker 3/14/17 Dep. Tr. 183:9–18; *see also generally* Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report.

His clinical experience, combined with his review of the peer-reviewed scientific literature, qualifies Dr. Parker "to opine on mesh's reaction to and effect on the human body." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4944702, at *3 (S.D.W. Va. Aug. 30, 2016) (rejecting plaintiffs' argument that board-certified urologist Brian Schwartz, M.D., is unqualified to offer opinions about material properties of mesh because he is not trained as a polymer scientist, medical device engineer, or pathologist and has not analyzed explanted mesh under a microscope).

It also qualifies him to offer opinions on the safety and efficacy of TVT-O and TVT-Secur. *See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493585, at *3 (S.D.W. Va. Aug. 25, 2016) (denying motion to exclude testimony of Melvin Anhalt, M.D., in part because his "extensive clinical experience, combined with a review of peer-reviewed literature, qualifies Dr. Anhalt to opine on mesh's reaction to and effect on the

human body, and relatedly, the safety and efficacy of mesh products"); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014) (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh based on his extensive clinical experience and citation to "numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); *Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *24 (S.D.W. Va. May 5, 2015) (finding pelvic surgeon qualified to offer opinions about the safety and efficacy of the Advantage Fit based on his clinical experience implanting 70 to 80 of defendant's sling products, his experience teaching other surgeons how to perform the surgery, his experience with competitors' products, and his review of the existing literature).

Based on this authority, there is no basis to find Dr. Parker unqualified to give opinions about mesh properties.

B. Dr. Parker's mesh-properties opinions are based on a reliable methodology.

Dr. Parker's opinions are supported by not only his clinical experience but also the numerous scientific studies, scientific articles, and statements of professional societies he relied on. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 7 (discussing studies showing poor outcomes before the introduction of the TVT); *id*. at 8–10 (discussing studies demonstrating the efficacy of TVT procedures); *id*. at 10–12 (discussing TVT-O studies); *id*. at 13–14 (discussing professional society statements); *id*. at 15–17 (discussing TVT-Secur studies). In reaching his opinions, he relied on the highest-level scientific evidence directly applicable to these products, including systematic reviews and meta-analyses. *See, e.g.*, *id*. at 8–9 (discussing 2009 and 2015 Cochrane Reviews); *id*. at 15–16 (discussing meta-analyses of TVT-Secur studies).

Plaintiffs do not specifically address any of these studies. Indeed, they do not mention a single scientific study or article by name in their memorandum. *See generally* Pls.' Mem. (Dkt. 3674). To the extent Plaintiffs challenge the reliability of Dr. Parker's opinions regarding the safety and efficacy of the TVT-O and TVT-Secur, the Court should deny their motion.

C. Dr. Parker's degradation opinions are well-supported.

Dr. Parker disagrees with Plaintiffs' experts that the material used in the TVT products degrades or is cytotoxic. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 18–19; *see also, e.g.*, Ex. 1, Parker 3/14/17 Dep. Tr. 176:21–178:18. Prolene has been commercially available since 1969, has been studied extensively, and is the "suture of choice" in surgical disciplines including cardiac, ophthalmologic, neurologic, orthopedic, and gynecologic surgeries. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 18. In Dr. Parker's opinion, "If there was substantial degradation, we would have already seen a clinical problem arise in not only one but likely all of these surgical disciplines. . . . If there was any sign of degradation of Prolene, the cardiothoracic surgeons would have replaced it with a different suture by now, or demanded a new suture to be developed." *Id*. Dr. Parker notes further that the polypropylene used in Prolene sutures and mesh "has been used to make surgical meshes for hernias for many years and there has been no clinical sign of breakdown of [these] meshes." *Id*.; *see also id*. (stating that he "ha[s] never seen a case of polypropylene causing cytotoxicity" and that "the medical literature is devoid of any study confirming clinical cytotoxic effects of polypropylene mesh slings").

Dr. Parker also reviewed the medical literature cited by Plaintiffs' experts and notes that none of the studies on which they rely have "found any clinical harm that has resulted from degraded mesh." *Id*.; *see also id*. at 18–19 ("[T]o opine that Prolene is cytotoxic not only ignores the thousands of studies on mesh that find it safe for human use; it also ignores the fact that Prolene sutures have been used for nearly 50 years in millions of patients as an approved foreign

body for surgical use."). On these bases, he concludes that "Prolene suture and mesh will continue to be viewed by the vast majority of the medical community as a stable, nonabsorbable, nondegradable product that is safe for human implantation." *Id*. at 18.

Plaintiffs challenge Dr. Parker's degradation opinions on the grounds that "they appear to be primarily based on the premise that since he himself has not identified a clinical outcome that in his mind correlates with degradation, then the mesh must not be degrading." Pls.' Mem. (Dkt. 3674) at 7. Plaintiffs do not support this conclusory assertion with any citation to Dr. Parker's report or deposition testimony. *Id*. And it ignores all of the support for these opinions discussed above, as well as Dr. Parker's testimony that, in forming his opinions, he reviewed and relied on medical literature that concludes that Prolene does not degrade. Ex. 1, Parker 3/14/17 Dep. Tr. 178:2–18.

Plaintiffs take issue with the "personal research" Dr. Parker conducted, but do not deny that he reviewed the materials provided by Ethicon, and they fail to provide any analysis or criticism of any of the studies on which he relies, or identify any studies or articles he failed to consider. Pls.' Mem. (Dkt. 3674) at 7; *see also* Ex. 1, Parker 3/14/17 Dep. Tr. 11:25–13:4 (estimating that he spent at least 30 hours on independent research and 40 hours reviewing the materials provided by Ethicon, and that he reviewed the majority of the materials provided). Plaintiffs state that "anything he has read with regards to degradation would have been included in his reliance materials" and assert that "the selective documents provided by Ethicon do not address degradation." Pls.' Mem. (Dkt. 3674) at 7–8. But Dr. Parker's reliance materials include numerous publications regarding degradation and whether polypropylene is inert. *See generally, e.g.*, Ex. E to Pls.' Mot. (Dkt. 3672-6), Parker Supplemental Reliance List; *see also* Ex. 1, Parker

3/14/17 Dep. Tr. 13:5–24 (noting that his supplemental list included additional items from Dr. Parker's research).

Plaintiffs' challenge amounts to little more than conclusory, unsupported assertions that Dr. Parker's opinions are unreliable. But, as shown, Dr. Parker's degradation opinions are adequately supported and will assist the jury in assessing the alleged defects and general and specific causation.

D. Dr. Parker's contracture and shrinkage opinions are reliable.

In Dr. Parker's opinion, mesh does not contract in the way that Plaintiffs' experts suggest. Ex. 1, Parker 3/14/17 Dep. Tr. 169:9–170:4 (discussing opinions and literature re mesh contracture or shrinkage). He bases these opinions not only on his own clinical experience but also on his review of studies that discuss in vivo changes to mesh. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 19; *see also* Ex. 1, Parker 3/14/17 Dep. Tr. 169:9–170:4 (discussing opinions and literature re mesh contracture or shrinkage). Relying on observations, clinically relevant contracture and shrinkage should manifest by women experiencing an inability to void over time after mesh implantation; instead, "the clinical data suggests the opposite, that over time there is a slow worsening of stress incontinence rates." Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 19. Nor is there clinical data showing the exponential increase in erosions one would expect to see if Plaintiffs' theory was correct. *Id*. Dr. Parker's opinion aligns with his clinical experience. *Id*. at 20. And he supports it further with his reliance on scientific studies that contradict Plaintiffs' theory. *Id*. at 19–20.

Plaintiffs challenge Dr. Parker's opinions on the grounds that "[a] doctor's personal experience claiming to have not seen evidence of mesh shrinkage or contracture cannot serve as a reliable scientific basis." Pls.' Mem. (Dkt. 3674) at 8. This is incorrect. *See Mathison v. Boston Scientific Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *28–29 (S.D.W. Va. May 6, 2015)

(holding that clinical experience of board-certified urologist, Dr. Lonny S. Green, and review of scientific literature were sufficiently reliable bases for his opinions that defendant's mesh product does not shrink or contract). Moreover, it ignores the other bases for Dr. Parker's opinions discussed above.

Plaintiffs also assert that Dr. Parker's opinions "are directly contrary to numerous published, peer-reviewed articles, which establish beyond reasonable scientific dispute the general acceptance of the phenomenon of in vivo mesh shrinkage." Pls.' Mem. (Dkt. 3674) at 9. Yet Plaintiffs do not cite a single article or study in support of this assertion. *Id.* And as Defendants have argued throughout this litigation, Plaintiffs' authorities do not support their theory that midurethral slings contract and shrink in vivo, let alone establish it beyond reasonable scientific dispute. *See, e.g.*, Defs.' Mem. in Opp'n to Pls.' Mot. to Exclude Certain Opinions and Testimony of Brian N. Schwartz, M.D. (Dkt. 2922) at 13–14 (noting that none of the nine articles cited by Plaintiffs studied mesh contracture and shrinkage of midurethral slings; all documented case series or animal studies involving other products).

As Dr. Parker explained, the substantial body of scientific literature and his own clinical experience are at odds with the idea that the mesh in midurethral slings contracts in a clinically significant way. Dr. Parker's opinions are reliable and should be admitted.

E. Dr. Parker's pore-size and weight opinions are adequately supported.

In his report, Dr. Parker addresses the choice of a Type I mesh for the TVT devices, citing the Amid study and other scientific articles in support of the appropriateness of the pore size of this mesh for this application. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 20. He also disagrees with Plaintiffs' experts' opinion that the TVT mesh is more harmful than lighter-weight meshes, based on his analysis of relevant scientific studies and documents regarding Ethicon's unsuccessful attempts to develop a lighter-weight, partially absorbable sling.

Id. at 20–21; *see also* Ex. 1, Parker 3/14/17 Dep. Tr. 180:19–182:24. Dr. Parker reviewed the medical literature and found no studies demonstrating that a lighter-weight mesh "would yield safer results than Prolene mesh when used as a sling to treat SUI." Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 21.

Plaintiffs challenge Dr. Parker's opinions on the grounds that he "only reviewed one document to gain his understanding of the pore size with regards to the TVT devices." Pls.' Mem. (Dkt. 3674) at 9. Plaintiffs then assert that Dr. Parker's opinions are based solely on his qualifications as a pelvic-floor surgeon and are therefore insufficiently supported. *Id*. The Court should reject these arguments. Plaintiffs mischaracterize Dr. Parker's bases for his opinions, which, as noted above, include not only his clinical experience and the document regarding pore size to which he referred, but also his review of medical literature relating to pore size and classification of mesh weight, studies of both characteristics, and other Ethicon documents. Plaintiffs have not identified any relevant study that Dr. Parker failed to consider or any purported flaw in his analysis.

Accordingly, the Court should reject Plaintiffs' challenge and find that Dr. Parker's opinions regarding pore size and mesh weight are adequately supported. These opinions will assist the jury in understanding the evidence regarding these mesh characteristics and will aid in determining whether Plaintiffs can meet their burden of proof on the issues of design defect and general and specific causation. The Court should find that Dr. Parker's opinions on these topics are the result of a reliable methodology, and admissible under *Daubert* and Rule 702.

F. Dr. Parker's opinions about laser-cut and mechanically cut mesh are reliable.

Dr. Parker believes that there is no clinically meaningful difference between laser-cut and mechanically cut mesh. Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 21. This opinion is

consistent with his clinical experience and the medical literature, which, in Dr. Parker's view, offers "no support for the opinion that there is a clinical difference between laser and mechanically cut mesh or that any of the alleged design defects associated with the cut," including particle loss, fraying, and stiffness, "are of any clinical significance." *Id.*; Ex. 1, Parker 3/14/17 Dep. Tr. 183:9–18 (testifying that he reviewed "hundreds and hundreds of studies" and saw no finding that the "laser cut quality of TVT-Secur was causing any increase in erosions or other complications"). He notes that studies both before and after laser-cut mesh was introduced "show similar complication rates—especially in terms of erosions." Ex. B to Pls.' Mot. (Dkt. 3672-2), Parker Report at 21.

Plaintiffs challenge the reliability of Dr. Parker's opinions because they claim he is unaware of the differences between laser-cut and mechanically cut mesh. Pls.' Mem. (Dkt. 3674) at 10. Although Plaintiffs quote several pages of Dr. Parker's testimony, they do not explain the significance of this testimony or how it supports their argument. *Id*. at 10–11. Plaintiffs appear to take issue with Dr. Parker's insistence that any purported defective mesh characteristic must be "clinically relevant," but do not explain how a characteristic that does not manifest clinically could possibly be the cause of any alleged injuries. *Id*. at 12.

Again, Plaintiffs offer nothing more than conclusory, unsupported assertions that Dr. Parker's opinions are unreliable. But Dr. Parker's mesh-cut opinions are well-supported by his extensive clinical experience and his thorough review of the medical literature. Plaintiffs' motion to exclude them should be denied.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Brian Parker, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 27, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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